REMARKS

Claims 48 -51 and 56 – 69 stand rejected under 35 U.S.C. 102(a) as being anticipated by Shusterman et al.(5,967,995).

Applicants respectfully disagree and request that this rejection be withdrawn for the following reasons.

Applicants respectfully submit that Shusterman et al. does not teach the claimed invention.

Shusterman et al. (US 5,967,995) claims to have a method to predict the likelihood of the onset of a life threatening cardiac arrhythmia (LTCA) using heart rate variability (HRV). This HRV information is a secondary signal derived from the RR intervals of the ECG of a patient during normal sinus rhythm. Shusterman includes a reference to wavelet processing of ECG signals, but this is in the context of the prediction of *the onset* of an arrhythmia. Shusterman also comments upon the usefulness of having such a predictive capacity in automatic external defibrillators.

In contrast, the present invention predicts the outcome of attempted cardioversion (the defibrillation shock) directly from the ECG. Hence, the claims currently under consideration relate *only* to the heart in a state of arrhythmia i.e. ventricular fibrillation and atrial fibrillation. Hence, in the present application:

- Claim 48 is specific to a "heart in Ventricular fibrillation"
- Claim 56 is specific to a "heart in Ventricular fibrillation after the commencement of Cardio-pulmonary resuscitation"
- Claim 63 is specific to a "heart in atrial fibrillation"

The invention of Shusterman relates only to ***pre-arrhythmia*** information extracted, possibly, from the patient ECG in order to predict the onset of arrhythmia. In complete contrast, intrinsic to the present invention, and specified in the claims at issue, is the assumption that the

subject is ***already in arrhythmia***. It should also be noted here that the HRV used by Shusterman cannot be derived during ventricular fibrillation because it is an arrhythmia.

In conclusion: (1) the claimed invention is not designed for use during normal sinus rhythm while Shusterman's cannot be used during fibrillation; (2) the claimed invention uses the ECG directly while Shusterman et al use the HRV derived from the ECG; and (3) Shusterman's invention predicts the onset of an arrhythmia, while the present invention predicts the outcome of defibrillation therapy. Hence, the respective inventions use different information during mutually exclusive heart rhythms, to predict different events. Accordingly, there can be no anticipation and the rejection should be withdrawn.

In view of the above and foregoing, it is respectfully submitted that the claims now on file are believed to be in condition for allowance, and prompt and favorable action is earnestly solicited. Should there be any question concerning this response or the application in general, the Examiner is respectfully urged to telephone the undersigned so that prosecution of this application may be expedited.

FEE AUTHORIZATION

The Commissioner is authorized to charge fee deficiencies or credit overpayments associated with this submission to the NIXON PEABODY LLP Deposit Account No. 50-0850.

Date: 01/10, 2005

Respectfully submitted,

David S. Resnick (Reg. No. 34,235)
NIXON PEABODY LLP
100 Summer Street
Boston, MA 02110-2131
Tel: (617) 345-6057
Fax: (617) 345-1300